

IN THE UNITED STATES PATENT AND TRADEMARK 9

In re Patent Application of

YAN et al

Atty. Ref.: 1889-34

Serial No. 09/694,011

Group: 1617

Filed: October 23, 2000

Examiner: Sharereh, S.

For: GAS MIXTURES USEFUL AS ULTRASOUND CONTRAST MEDIA

CONTRAST AGENTS CONTAINING THE MEDIA AND METHOD

May 8, 2003

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

Applicants submit this Information Disclosure Statement pursuant to 37 C.F.R. §§ 1.97 and 1.98 in order to comply with the duty of disclosure under 37 C.F.R. § 1.56. These references are listed on the attached modified PTO Form No. 1449. It is requested that the information be expressly considered during the prosecution of this application and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom. A copy of each of these references has already been provided to the Examiner in the file of Serial No. 08/740,653.

Applicants direct the Examiner's attention to the several pending and resolved interferences relating to the general subject matter of this application, including the January 31, 2003 "Decision on Motions; Show Cause Order" which was issued from The Board of Appeals and Patent Interferences in Interference Nos. 103,880, 103,881 and 104,154. Among the decisions rendered in these papers were orders to show cause concerning the patentability of the parties' claims. Applicants encourage the Examiner to consider these interferences, including Applicants' other interferences and interference requests. Applicants understand that the Examiner has access to the Decision on Motions; Show Cause Order and any other papers related to interferences. If the Applicants can be of service in providing additional information or copies of the papers, Applicants would be pleased to help.

YAN et al Serial No. 09/694,011

No fee is required. If there are additional fees, please charge them to our firm Deposit Account No. 14-1140.

Respectfully submitted,

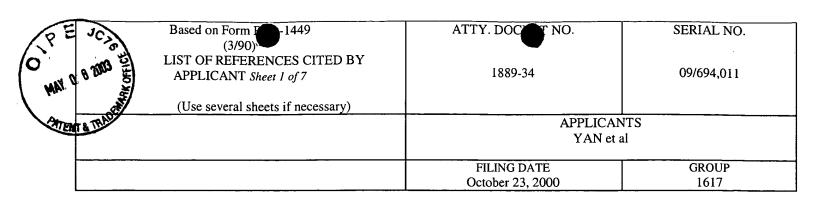
NIXON & VANDERHYE P.C.

By:

Arthur R. Crawford Reg. No. 25,327

ARC:eaw 1100 North Glebe Road, 8th Floor

Arlington, VA 22201-4714 Telephone: (703) 816-4000 Facsimile: (703) 816-4100



		U.S. PA	TENT DOCUMENTS			
EXAMINER INITIAL	DOCUMENT NUMBER	ISSUE DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	5,730,954	3/24/98	Albayrak et al.			
	5,599,523	2/4/97	Beller		RECE	11/10
	4,832,941	5/23/89	Berwing		1	IVEU
	5,711,933	1/27/98	Bichon et al.		MAY 0	
	4,957,656	9/18/90	Cerny	120	TIMAL OF	2003 1600/2900
	4,684,479	8/4/87	D'Arrigo	146	A CENTE	
	4,859,363	8/22/89	Davis		TACIALE!	1600/2900
	3,615,972	10/26/71	Morehouse			- 400/2000
	5,137,928	8/11/92	Erbel			
	5,190,982	3/2//93	Erbel			
	5,205,287	4/27/93	Erbel		†	
	4,370,349	1/25/83	Evans			
	4,718,433	1/12/88	Feinstein			
	4,572,203	2/25/86	Feinstein			
	4,774,958	10/4/88	Feinstein			
	5,049,322	9/17/91	Fessi			
	5,283,067	1/1/94	Geller			
•	5,147,631	9/15/92	Glajch et al.		<u> </u>	
	5,364,612	11/15/94	Goldenberg			
	5,089,181	2/18/92	Hauser		<u> </u>	
	4,466,442	8/21/84	Hilmann et al.			
	5,529,766	6/25/96	Klaveness		<u> </u>	
	5,536,490	7/16/96	Klaveness			
	5,567,413	10/22/96	Klaveness			
	5,558,856	9/24/96	Klaveness et al.		1	
	3,650,831	N/A	Jungermann		-	
	5,552,133	9/3/96	Lambert et al.			
	5,536,489	7/16/96	Lohrmann			-
	5,716,597	2/10/98	Lohrmann et al.			-
	4,927,623	5/22/90	Long		1	
	4,192,859	3/11/80	Mackaness, et al			
	4,027,007	5/3177	Messina			
	5,601,085	2/11/97	Østensen		1	
	4,235,871	11/25/80	Papahadjopoulos, et al.	· · -	 	
	5,409,688	4/25/95	Quay			
···· -	5,393,524	2/28/95	Quay		-	
	4,442,843	4/17/84	Rasor			
	4,657,756	4/14/87	Rasor		 	
	4,681,119	7/21/87	Rasor			
	4,001,119	1/21/0/		l		I

EXAMINER	DATE CONSIDERED
* EXAMINER: Initial if reference considered, whether or not	citation is in conformance with MPEP 609. Draw line through
citation if not in conformance and not considered. Include conv	of this form with next communication to applicant

DATE CONSIDERED



Based on Form P 1449
(3/90)
LIST OF REFERENCES CITED BY
APPLICANT Sheet 2 of 7

1889-34

ATTY. DOC

SERIAL NO.

09/694,011

(Use several sheets if necessary)

APPLICANTS YAN et al

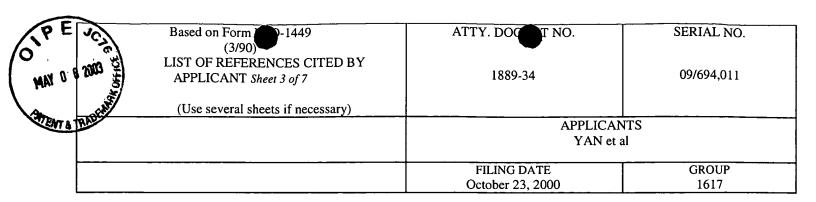
NO.

FILING DATE GROUP October 23, 2000 1617

5,141,738	8/25/92	Rasor			
5,425,366	6/20/95	Reinhardt			
5,501,863	3/26/96	Rössling et al.			
5,593,687	1/14/97	Rössling et al.			
4,544,545	10/1/85	Ryan			
4,900,540	2/13/90	Ryan et al.			
4,224,179	9/23/80	Schneider			
4,229,360	10/21/80	Schneider	RF	CEIV	ED
5,271,928	12/21/93	Schneider		I V	LU
5,312,615	5//17/94	Schneider	م مه		
5,380,519	1/10/95	Schneider	TEQU.	1 0 2 5	03
5,413,774	5/9/95	Schneider	- CH C	FNTED	
5,445,813	8/29/95	Schneider		* 0 9 20 ENTER 16	00/2 900
5,531,980	7/2/96	Schneider			
5,643,553	7/1/97	Schneider	1		1
5,658,551	8/19/97	Schneider			
5,567,414	10/22/96	Schneider			
5,639,443	6/17/97	Schutt et al.			
5,195,520	3/23/93	Schlief			
5,380,411	1/10/95	Schlief			
5,670,135	9/23/97	Schroder			
 3,900,420	8/19/75	Sebba			
3,968,203	7/6/76	Spitzer			
5,425,366	6/20/95	Stein			
 4,265,251	5/5/81	Tickner			
4,316,391	2/23/82	Tickner			
4,276,885	7/7/81	Tickner et al.			
5,088,499	2/18/92	Unger			
5,123,414	6/23/92	Unger			
5,149,319	9/22/92	Unger			
5,209,720	5/11/93	Unger			
5,228,446	7/20/93	Unger			
5,874,062	2/23/99	Unger			
5,776,429	7/7/98	Unger et al.			
5,352,436	10/4/94	Wheatley	I		
4,844,882	7/4/89	Widder et al.			
5,556,610	9/17/96	Yan et al.			

EXAMINER	DATE CONSIDERED

^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



		FOREIGN PAT	TENT DOCUMENTS				
	DOCUMENT NUMBER	PUBLIC- ATION DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLA	ATION
						YES	NO
	ZA 910961		South Africa			IVED 2003	
	(Albayrak)			1 .	HFO-		
	EP A 458 745	11/27/91	EP		705	VED	
	(Bichon et al.)				MAY		
	EP 359 246 A2	3/21/90	EP	\$CL	77 09	200	
	(Cerny)			77	CEAL	<i>1003</i>	
	EP 359 246 A3	3/21/90	EP		-WER .		
	(Cerny)				1 1/1	00/2000	
	GB 1,044,680 (Dow	10/5/66	Great Britain			V/2000	
	Chemical)						
	WO 84/02838	8/2/84	PCT				
	(Feinstein)						
	WO 89/05160 (PCT	6/15/89	PCT			X	
	DE 988/00751)						
	(Fritzsch)				·		
	WO 92/05806	4/16/92	PCT				
	(Giddey)						
	WO 92/19273 (EP 0	11/12/92	PCT				
	583 390)						
	(Goldenberg)						
	DE A 41 27 442	2/18/93	Germany			X	
	(Gross)						
,	CA 1239092	7/12/88	Canada				
	(Hilmann)						
	CA 1232837	2/16/88	Canada				
	(Hilmann)				<u> </u>		
	WO 91/12823	9/5/91	PCT				
	(Illum et al.)				ļ		4
	WO A 92/17212	10/15/92	PCT				
	(EP 0 576 519)						
	(Klaveness)	10/15/100					.
	WO 92/17213 (EP 0	10/15/92	PCT				
	576 521)				1		
	(Klaveness)	10/10/02	DOM		 		
	WO 92/21382 (EP 0	12/10/92	PCT		1		
	586 524)				}		
	(Klaveness)	2/4/02	<u> </u>		 		
	CA 2077383	3/4/93	Canada				
	(EP 0535387)				1		
	(Krone)				L	l	

* EXAMINER:	Initial if reference considered,	whether or not ci	tation is in conform	ance with MPEP 609.	Draw line through
citation if not in o	conformance and not considered	d. Include copy o	f this form with nex	t communication to apr	olicant.

EXAMINER

DATE CONSIDERED



Based on Form P 1449 (3/90) LIST OF REFERENCES CITED BY APPLICANT Sheet 4 of 7

1889-34

ATTY. DOC

SERIAL NO.

09/694,011

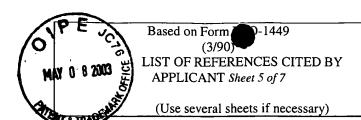
(Use several sheets if necessary)

APPLICANTS YAN et al

FILING DATE	GROUP	
October 23, 2000	1617	
PCT		

WO 93/5819 (EP 0 605 477)	4/1/93	PCT				
(Quay)						
WO 94/16739	8/4/94	PCT				
(Quay)						
WO 88/7365	10/6/88	PCT		h	ECEIVAN AND PROPERTY OF THE PR	
(Ranney)				_	-UEIL	~
EP A 131 540	1/16/85	EP		> M	X	
(Rasor & Tickner)				150	19	
GB 213 5647	9/5/84	Great Britain		The state of the s	100	†
(Ridgway)				٠,	VIFO	
WO 91/15244	10/17/91	PCT			1600	
(Schneider et al)				_	00/2	
EP A 554 213	4/8/93	EP				
(Schneider)						
WO-A-85/02772	7/4/85	PCT				
(Schroder)						
NZ 253115	1/26/96	New Zealand				
 (Stein)			·			
WO 92/18164	10/29/92	PCT				
(Sutton)						
WO-A-80/2365	11/13/80	PCT				
(Tickner et al.)						
WO 91/09629	7/11/91	PCT				1
(Unger)						
WO 92/22247	12/23/92	PCT				
(Unger)						
WO 92/17514	10/15/92	PCT				
(Unger)	<u> </u>					<u> </u>
WO 93/06869	4/15/93	PCT				
(Vanderipe)						
EP A 324 938	7/26/89	EP				
(Widder et al.)						L

EXAMINER	DATE CONSIDERED
* EXAMINER: Initial if reference considered, whether or not	citation is in conformance with MPEP 609. Draw line through
citation if not in conformance and not considered. Include copy	of this form with next communication to applicant.



ATTY. DOO T NO.

1889-34

SERIAL NO.

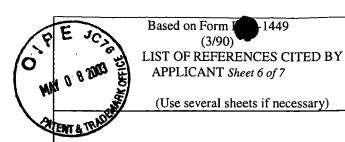
09/694,011

APPLICANTS YAN et al

FILING DATE October 23, 2000 GROUP 161RECEIVE

	OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)	TECH CENTY
	Biochemistry/Ed. Stryer - 2 Ed., San Francisco, Freeman, pp. 208-09 (1981)	CFNITH
	Concise Encyclopedia Of Polymer Sci. and Engin., Wiley, pp. 12-13 (1990)	
	Encyclopedia of Polymer Science and Engineering, 2nd ed., 10, p. 95, Wiley & Sons, 1987)	
	Encyclopedia of Polymer Science and Engineering, pp. 164-69, Wiley & Sons, 1985	
	""Freon" Fluorocarbons Properties and Applications," <u>DuPont Technical Bulletin</u> , pp. 1-11 (1	1964)
	""Freon" <u>DuPont Technical Bulletin</u> , pp. 1-10 (1987)	<u> </u>
	Gas Encyclopedia, Elsevier Publishier (1976), CCIF3	
	Handbook of Pharmaceutical Excipients: Am. Pharm. Ass. 181-183 (1986)	
	"Lecithin" in Rompp Chemie Kexikon, p. 2474 (1989-92)	
	"Lecithin" in Blakiston's Gould Medical Dictionary, 4th Ed., N.Y., Mcgraw-Hill,, p. 749 (197	(9)
	"Lecithin" in Dorland's Illustrated Medical Dictionary, 26 Ed., Philadelphia, Saunders, p. 721	
	Remington's Pharmaceutical Sciences: Mack Publ. Comp., 295-298: 736; 1242-44 (1975)	· · · · · · · · · · · · · · · · · · ·
	Barnhart et al., Invest. Radiol, 25, 162-164 (1990) "Characterics of Albunex"	
	Benita et al., <u>Journal of Pharmaceutical Science</u> , 73, pp. 1721-1724 (1984) "Characterization of	of Drug
	Loaded Polydilactide Microspheres"	
	Bleeker, et al., <u>J. Acoust. Soc. Am.</u> , 87 (4), Apr. 1990, pp. 1792-1797, "Ultrasonic characteriz	ation of
	Albunex [®] "	
	Bleeker, et al., 1990 J. Ultrasound Med., 9:461-471, (1999), "On the Application of Ultrasonic	Contrast
L	Agents "	
	Bommer et al., Abstract of the 54 Scient. Sessions, Circulation <u>64</u> , - 203, Abst. 770 (1981)	
	Crommelin et al., Pharm. Res., pp. 159-163 (1984) "Stability of Liposomes on Storage"	
	Crommelin et al., Liposomes as Drugs Carriers Symp., pp. 88-93 (1986) "Freezing and Freeze	Drying of
	Liposomes"	
	de Gruyter, "Phospholipids", Concise Encyclopedia of Biochemistry, Berlin, pp. 348-49 (1983)	3)
	deJong, et al., <u>Ultrasonics</u> , 1992, Vol. 30, No. 2, pp. 95-103, "Absorption and scatter of encaps	sulated gas
	filled microspheres"	
	deJong, et al., <u>Ultrasonics</u> , 1991, Vol. 29 Jul., pp. 324-330, "Principles and recent development	nts in
<u> </u>	ultrasound"	
	Edwards, et al. <u>J. Acoust. Soc. Am.</u> , Vol. 70, No. 3 (1983), "Scattering of focused ultrasound	by spherical
	microparticles"	
	Epstein, et al., <u>J. Chem. Physics</u> , Vol. 18, No. 11, pp. 1505-1509, Nov. 1950, "On the Stability	of Gas
	Bubbles in Liquid-Gas Solutions"	
	Feinstein, et al., <u>JACC</u> , Vol. 16, No. 2, 8/90:316-24, "Safety and Efficacy of a New Transpuln	
	Ultrasound Agent", Amer. Hearts Assn. Monograph Circulation, Part II, Vol. 72, No. 4, Oct	. 1985,
	Abstracts of the 58 th Scientific Ses.	
	Feinstein, et al., Am. J. of Physiologic Imaging, 1:12-18 (1986), "Myocardial Contrast Echoca"	irdiography
	Enjagrain Lof the Amon Cell of Condiel 9,251,252 (1096) "Museculial Desfinitor Imagina	,,
	Feinstein, J. of the Amer. Coll. of Cardiol, 8:251-253 (1986) "Myocardial Perfusion Imaging.	
	H. Fessi, et al., "Nanocapsule formation by interfacial polymer deposition," <u>Int. J. Pharm.</u> , 155 No. 1, pp. R1 R4	1989, Vol.
	55, No. 1, pp. R1-R4	
	Fieser and Fieser, Organic Chemistry, 3rd ed. (1956) p. 847	n d
	Fobbe, et al., <u>Furtschr Rontgenstr</u> , 154.3 (1991) 242-245, "Farbkodierte Duplexsonographic u Ultraschallkontrast mittel"	na
L	Ouaschankontrast mitter	

EXAMINER	DATE CONSIDERED
* EXAMINER: Initial if reference considered, whether or not	citation is in conformance with MPEP 609. Draw line through
citation if not in conformance and not considered. Include copy	of this form with next communication to applicant.



1889-34

ATTY. DOC

SERIAL NO.

09/694,0 RECEIV MAY 0 9 20 ECH CENTER 1601

APPLICANTS YAN et al

FILING DATE GROUP 1617 October 23, 2000.

Ganguly et al., "Structure of hollow polystyrene microspheres" J. Microencapsulation, Vol. 6, No. 2, 193-198 (1989)
Gardner, et al., (1988), "A Survey of Intraocular Gas Use in North America," Arch. Ophthalmol., 106:1188-1189
Goldberg et al., Radiology, 177, pp. 713-7 (1990) "Hepatic Tumors"
Gregoriadis, Gregory, <u>Liposome Technology</u> , Volume I, "Preparation of Liposomes", CRC Press., pp. 172-77.
Helzel, Fortschr. Rontgenste, 140, pp. 337-340 (1984) "Erste Erfahrurgen"
Henry-Michelland et al., Colloids and Surfaces, 14, pp. 269-276 (1985) "Lyophilization and Rehydration of Liposomes"
Jacobs, "Intraocular gas measurement using A-scan ultrasound," <u>Current Eye Research</u> , Vol. 5, No. 8, 1986, pp. 575-578
Keller et al, <u>Circulation Res</u> , <u>65</u> , 458-467 (1989) "The Behavior of Sonicated Albumin"
Krause et al., <u>International Journal of Pharmaceutics.</u> , <u>27</u> , pp. 145-155 (1985) "Polylactic acid nanoparticle"
Levene et al, J. Acoust. Soc. Am., 87 (Suppl) 69 (1990) "Characterization of Albunex"
Lincoff, et al., "Intravitreal Longevity of Three Perfluorocarbon Cases, Arch. Ophthalmology, 98:1610-1611 (1980)
Lincoff, et al., "Intravitreal Expansion of Perfluorocarbon Bubbles," <u>Arch. Ophthalmology</u> , 98:1646 (1980)
Lincoff, et al., "The Perfluorocarbon Gases in the Treatment of Retinal Detachment," Ophthalmology, 90(5):546-551 (1983)
Lincoff, et al., "Perfluoro-n-butane: A Gas for Maximum Duration Retinal Tamponade," <u>Arch.</u> <u>Ophthalmology</u> , 101:460-463 (1983)
K. Makino, "Preparation and in vivo degradation properties," Chem. Pharm. Bull., (1985), Vol. 33, No. 3, pp. 1195-1201
Mattrey et al., Radiology, 148, pp. 759-762 (Dec. 1982) "UHM Sound; Perfluoroctylbr omide"
Chem Abs., Vol. 102. No. 3, 21 (Jan. 1985), Maynard et al., "Ultrasonic absorption by liposomes"
Meltzer, et al., <u>Ultrasound in Med. & Biol.</u> , Vol. 7, No. 4, pp. 377-384, 1981, "Transmission of Ultrasonic Contrast Through the Lungs"
Miller et al., J. Amer. Soc. Anesthesiol., 36 339-351 (1971) "Physicochemical Approaches"
Möhwald, <u>Annu. Rev. Phys. Chem.</u> , 41, 441-76 (1990) "Phospholipid and Phospholipid-Protein Monolayers At The Air/Water Interface"
Murrell et al, "Properties of liquids and solutions", Wiley, p. 276 (1982)
Nomura, et al., "US Contrast Enhancement of Hepatic Tumor with Helium Gas Microbubbles: A Preliminary Report," Jpn. J. Med. Ultrasonics, Vol. 18, No. 5, 1991, pp. 444-450
O'Hara et al, <u>Journal of Membrane Science</u> , 23 (1985) 1-9, "Preparation of ethylcellulose"
Ohta, et al., <u>Jpn. J. Med. Ultrasonics</u> , Vol. 18, No. 4 (1991), "Effect of the Contrast Agent and the Agitation Met."
Ophir, et al., <u>Ultrasound in Med. &Biol.</u> , Vol 15, No. 4, pp. 319-333, 1989, "Contrast Agents in Diagnostic Ultras."
Ostro in Spektrum d. Wiss, 94-95, 98 (Marz 1987). "Liposomen"
Özer et al., Acta Pharm. Tech. 34, pp. 129-139 (1988) "Influence of Freezing and Freeze Drying on Stability of Liposome"
 The state of the s

	EXAMINER	DATE CONSIDERED
* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through		
	citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	



Based on Form (3/90)LIST OF REFERENCES CITED BY APPLICANT Sheet 7 of 7

(Use several sheets if necessary)

ATTY. DOC

1889-34

APPLICANTS YAN et al

FILING DATE	GROUP
October 23, 2000	1617

	Park, et al., Journal of Chemical And Engineering Data, Vol. 27, No. 3 (1982), "Solubility of Gases in	
Liquids. 14. Bunsen Coefficients for Several Fluorine-Containing Gases (Freons) Dissolved		
	298.15K"	
	Peters et al., Am. J. Ophthalmol. 100 pp. 831-839 (1985) "The non expansive, equilibrated concentration	
of perfuoropropane in the eye"		
	Puisieux et al., Bull. Soc. Pharm. Bordeaux, 123, pp. 111-126 (1984) "Les Liposomes"	
	Rompp Lex. Chemie. 8 Aufl. Stuttgart: Franckh; Bd. Z: Cm-G, (1981): Bd 3; H-L, (1983); Bd 4, M-Pk (1985) "Porositat"	
	Rompps Chemie Lexikon, "Phospholipide"	
	Schlief, Current Opinion in Radiology, 1993, 3:198-207, "Ultrasound Contrast Agents"	
	Schneider, et al., Investigative Radiol., <u>26(1)</u> , pp. S190-91 (1991) "A New Ultrasound Contrast Agent Based on Biodegradable Polymers Microballoon"	
	Schneider, et al., Investigative Radiol., <u>29(2)</u> , pp. S149-51 (1991) "The Use of Polymers Microballoons as Ultrasound Contrast Agent"	
	Swanson, pp. 682-687, "Chapter 22: Enhancement Agents for Ultrasound: Fundamentals,"	
	Pharmaceuticals In Medical Imaging, (1990)	
	Szoka et al, PNAS 75, pp. 4194-4198 (Sept. 1978) "Procedure for preparation of Liposomes"	
	Tomlinson, Int. J. Pharm. Tech. & Prod. Mfr., 4, pp. 49-57 (1983) "Microsphere Delivery Systems"	
	Ulmius et al, Biochem., 21, p. 1553 (1982) "Molecular organization"	
	K. Uno, et al., "A new method of preparing monocored," <u>J. Microencapsulation</u> , 1984, Vol. 1, No. 1, pp. 3-8	
	Violante, et al., <u>Investigative Radiology</u> , Vol. 26, Nov. Supp 1991, "Particle-Stabilized Bubbles for Enhanced Organ Ultrasound Imaging"	
Voigt et al., "Lzithine" in Lehrb. d. pharm. Tech. i, uberarb. Aufl Weinheim; VCH, p. 367 (1979) Wheatley et al, Biomaterials 11, pp. 713-17 (1990) "Contrast agents for diagnostic ultrasound"		
Ultrasound "		
	Fiedler, Lexikon der Hiffstoffe, 4, Auflage, 1182-85	
Zhang, et al., J. East China Inst. Chem. Tech., 12(3) 343-345 (1986) "A Study on the Solubilities of		
	and C2F4 in Aqueous Solutions of HCl and NaCl"	
	Zeghlouol et al, Journal de Chimie Physique, 83; 665-671 (1986) "NMR And Microcalorimetry Study Of	
	The Solubility Of Certain Halons And Their Interaction with Human Serum Albumin"	

EXAMINER	DATE CONSIDERED	

^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.